

900 KAR 6:100. Certificate of need standards for implementation and biennial review.

RELATES TO: KRS 216B.015, 216B.086

STATUTORY AUTHORITY: KRS 194A.030(1)(c)4., 216B.040(2)(a)1, 216B.086

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)1 requires the Cabinet for Health and Family Services to administer Kentucky's Certificate of Need Program and to promulgate administrative regulations as necessary for the program. KRS 216B.086 authorizes the revocation of certificate of need, or portion thereof, for failure to implement the project in accordance with timetables and standards established by administrative regulation. This administrative regulation establishes the required timetables and standards for implementation as well as requirements for biennial reviews for the orderly administration of the Certificate of Need Program.

Section 1. Definitions. (1) "Cabinet" is defined by KRS 216B.015(6).

(2) "Days" means calendar days, unless otherwise specified.

(3) "Long-term care beds" means nursing home beds, intermediate care beds, skilled nursing beds, nursing facility beds, and Alzheimer nursing home beds.

(4) "Office of Inspector General" means the office within the Cabinet for Health and Family Services that is responsible for licensing and regulatory functions of health facilities and services.

(5) "Show cause hearing" means a hearing during which it is determined whether a person or entity has violated provisions of KRS Chapter 216B.

Section 2. Standards for Implementation. (1) As a condition for the issuance of a certificate of need, a holder of a certificate of need shall submit progress reports on the CON - Form 8, Certificate of Need Six Month Progress Report, incorporated by reference in 900 KAR 6:055, at the six (6) month intervals specified in this section.

(2) A notice specifying the date each progress report is due shall be sent to every holder of a certificate of need whose project is not fully implemented.

(3) The cabinet or its designee shall review a progress report and shall determine:

(a) If the required elements have been completed; and

(b) If the required elements have not been completed, whether sufficient reasons for failure to complete have been provided.

(4) A certificate of need shall be deemed complete if:

(a) The project has been approved for licensure or occupancy by the Office of Inspector General;

(b) A final cost breakdown has been submitted; and

(c) The required progress report fee pursuant to Section 3 of this administrative regulation has been submitted.

(5) Until a project is deemed complete by the cabinet, the cabinet may require:

(a) The submission of additional reports as specified in subsections (16) through (18) of this section; or

(b) Progress reports in addition to those required at six (6) month intervals under the provisions of this section.

(6) Except for a long-term care bed proposal, a certificate of need shall not be revoked for failure to complete the items required during a six (6) month period if the holder of the certificate of need establishes that the failure was due to circumstances that:

(a) Could not reasonably be anticipated and avoided by the holder; or

(b) Were not the result of action or inaction of the holder.

(7) If the cabinet determines that required elements have not been completed for reasons other than those set forth in subsection (6) of this section, it shall notify the holder of the certificate of need, in writing, that it has determined to revoke the certificate of need.

(8) The revocation shall become final thirty (30) days from the date of notice of revocation unless the holder requests a hearing pursuant to KRS 216B.086.

(9) The first progress report for any project other than long-term care beds shall include:

(a) For a project for the addition of new services or expansion of existing services that does not involve construction, renovation, or the installation of equipment: plans for implementation of the project;

(b) For a project for the purchase of equipment only: a copy of the purchase order;

(c) For a project involving the acquisition of real property: evidence of an option to acquire the site; or

(d) For a construction or renovation project: evidence that schematic plans have been submitted to the Public Protection Cabinet, Department of Housing, Buildings, and Construction, and the Office of Inspector General, Division of Healthcare.

(10) For a project other than long-term care beds not deemed complete, a second progress report shall include:

(a) For a project converting beds: documentation that all beds are licensed;

(b) For a project for addition of new services or expansion of existing services that do not involve construction, renovation, or the installation of equipment: documentation of approval for licensure and occupancy by the Office of Inspector General, Division of Healthcare, or the Kentucky Board of Emergency Medical Services; or

(c) For a construction or renovation project: the schedule for project completion, evidence of preliminary negotiation with a financial agency, and evidence of preliminary negotiation with contractors.

(11) For a project other than long-term care beds not deemed complete, a third progress report shall include:

(a) For a construction or renovation project:

1. A copy of the deed or lease of land;

2. Documentation of the final enforceable financing agreement, if applicable;

3. Documentation that final plans have been submitted to the Public Protection Cabinet, Department of Housing, Buildings, and Construction, and the Office of Inspector General, Division of Healthcare; and

4. An enforceable contract with a construction contractor; or

(b) For a project for purchase of equipment only: evidence of approval for licensure and occupancy by the Office of Inspector General, Division of Healthcare.

(12) For a project other than long-term care beds not deemed complete, a fourth progress report shall include documentation of final plan approval by the Public Protection Cabinet, Department of Housing, Buildings, and Construction, and the Office of Inspector General, Division of Healthcare, and evidence that construction has begun.

(13) For a project other than long-term care beds not deemed complete, a fifth progress report shall include documentation that construction or renovation is progressing according to schedule.

(14) For a project other than long-term care beds not deemed complete, a sixth progress report shall include documentation that the project has been approved for licensure or occupancy by the Office of Inspector General, Division of Healthcare, and, if required, that the appropriate license has been approved for the health care service or facility.

(15) For a project other than long-term care beds not deemed complete after the sixth progress report, the certificate holder shall, upon request, provide the cabinet or its designee

with a written statement showing cause why the certificate should not be revoked. The cabinet may defer revocation action upon a showing by the certificate holder that the project shall be completed on a revised schedule. The cabinet or its designee may require additional progress reports.

(16) For a project involving long-term care beds, the progress reports required by this subsection shall be submitted.

(a) The first progress report shall include:

1. A copy of the deed or lease of land for a project requiring acquisition of real property; and
2. Evidence that final plans have been submitted to the Public Protection Cabinet, Department of Housing, Buildings, and Construction, and the Office of Inspector General, Division of Healthcare.

(b) For a project involving long-term care beds not deemed complete, a second progress report shall include:

1. For a conversion of bed project: documentation that the beds in the project are licensed; or
2. For a construction project:
 - a. A schedule for project completion with projected dates;
 - b. Documentation of final financing;
 - c. Documentation of final plan approval by the Public Protection Cabinet, Department of Housing, Buildings, and Construction, and the Office of Inspector General, Division of Healthcare; and
 - d. An enforceable construction contract.

(17) For a project involving long-term care beds not deemed complete, a third progress report shall include documentation that construction or renovation is progressing according to the schedule for project completion.

(18) For a project involving long-term care beds not deemed complete, a fourth progress report shall include documentation that the project has been appropriately licensed and approved for occupancy by the Office of Inspector General, Division of Healthcare.

(19) The cabinet or its designee may grant no more than three (3) additional extensions of six (6) months for good cause shown if the certificate holder of long-term care beds has failed to comply with the relevant progress report requirements established in this section.

(20) If the project involves a capital expenditure, a final cost breakdown shall be included in the final progress report.

(21) If the Office of Inspector General, Division of Healthcare, discovers a violation of terms and conditions listed on a certificate of need and license while it is conducting its annual licensure inspection, it shall refer this violation for a show cause hearing in accordance with 900 KAR 6:090, Section 4.

Section 3. Progress Report Fee. (1) A progress report fee in the amount of \$100.00 or one (1) percent of the application fee assessed pursuant to 900 KAR 6:020, whichever amount is greater, shall be submitted by the certificate of need holder with each semi-annual progress report filed for each certificate of need that has been issued for more than three (3) years.

(2) A certificate of need shall be revoked for failure to submit the progress report fee.

Section 4. Voluntary Revocation of a Certificate of Need. If a certificate of need holder requests revocation of a certificate of need or a portion of a certificate of need and submits a new application for the same proposed health facility or service within five (5) years from the date of revocation, the cabinet shall apply the application fee that was submitted for the revoked certificate of need or portion of a certificate of need toward the fee assessed pursuant

to 900 KAR 6:020 for the new application.

Section 5. Biennial Review. (1) A certificate of need holder may be subject to biennial review to determine if the holder is in compliance with the terms as listed on the certificate of need.

(2) Biennial review may be conducted within sixty (60) days of the second anniversary of the final progress report and at twenty-four (24) month intervals thereafter.

(3) The cabinet or its designee shall provide sixty (60) days' advance written notification to the subject of any biennial review, including the following:

(a) When the biennial review will be initiated;

(b) Request for information necessary for the review to which the cabinet does not have ready access; and

(c) A deadline for a response to the request for information.

(4) If the cabinet finds that any of the terms and conditions of a certificate of need approval and license have been violated, the review of, and any sanctions for, this violation shall be conducted in accordance with 900 KAR 6:090, Section 4. (36 Ky.R. 250; Am. 815; eff. 10-21-2009 42 Ky.R. 1643; eff. 2-5-2016; 47 Ky.R. 1698, 2597; eff. 6-16-2021.)